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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/971,627	10/09/2001	Thomas Conrad Mack	N1388-017	4202

32905 7590 01/30/2003

JONDLE & ASSOCIATES P.C.
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CENTENNIAL, CO 80112

EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 01/30/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/971,627

Applicant(s)

MACK ET AL.

Examiner

Medina A Ibrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 04 October 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-32 are pending and are under examination.

Objections

2. The specification is objected to because of the following: the statement of deposit in the specification, page 37, does not comply with the deposit requirement set forth in 37 CFR 1.801-1.809. The deposit statement must be amended to include the inbred line with the deposit accession no.
3. Claims 1, 17, and 19 (and dependents 2-16, 18 and 20-32) are objected to for failing to recite complete Accession information of the claimed inbred line. The ATCC accession no must be filled in as appropriate.

Claim Rejections - 35 USC § 112, 2nd

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 6, 8-11, 17-25, and 28-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is indefinite in the recitation of "wherein said plant is male sterile" because the claims from which claim 5 depends are not drawn to a male sterile plant.

Claim 8 is indefinite because "the cells or protoplasts of the tissue culture" lacks antecedent basis. It is suggested that "the cells or protoplasts of the tissue culture being from a tissue " is replaced with ---wherein the tissue culture is---.

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In claim 9, "capable of expressing" implies the plant may or may not express all the morphological and physiological characteristics of the inbred line 2JK221. It is suggested that "is capable of expressing" be replaced with --- has ---.

Claims 10, 24 and 30 recite "using" or "utilizing" without any positive method steps by which one could practice the claimed method. Claim 30 is indefinite for lacking defined method steps. Dependent claims 31- 32 are included in the rejection.

In claim 11, " second said parent" should be changed to --- said second parent---, for proper dependency.

Claims 17-18 are indefinite for failing to recite the steps for identifying plants with decreased vigor.

Claims 19 -25 are indefinite because the metes and bounds of what is retained in "2JK221-derived" corn plants or parts thereof are unclear. Would "derived" mean "isolated" or "progeny" or something else? What is encompassed in the derived product is unclear.

Claims 20, 23, 25, and 29 are indefinite in the recitation of "above average", "high", "good", which are relative terms lacking comparative basis; "adapted" is also indefinite.

In claim 28, the limitation "corn plants" lack antecedent basis in claim 27.

Claim 31 is indefinite in the recitation of "The corn plant breeding program of claim 30" because claim 30 is drawn to a method for developing a corn plant rather than a breeding program.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Since the seed claimed is essential to the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be readily available to the public. The specification does not disclose a reproducible method to obtain the exact same seed and it is unclear if the seed is readily available to the public.

The statement on page 37 of the specification indicating Applicant's intention to make an enabling deposit of the claimed invention with ATCC is noted. However, there is no indication that the seed has been deposited and no indication that the seed is available to the public. A deposit of at least 2500 seeds is required for enablement purpose.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or statement by an attorney of record over his or her signature and registration number, stating that the seed has been deposited under the Budapest Treaty and the seed will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit

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requirement made herein. See 37 C.F.R. 1.808-1.809 for additional explanation of these requirements.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, Applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 days or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (see C.F.R. 1.807); and

(e) the deposit will be replaced if it should ever become unviable.

8. Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim is drawn to a corn plant of the inbred line 2JK221 which is male sterile. The claim reads on a single gene conversion plant comprising a single gene trait introgressed into the claimed variety by back crossing or other traditional means.

Applicant only provides guidance for the inbred corn plant and seed of the inbred corn line designated as 2JK221, and a method for producing progeny plants by crossing said plant with plants of another corn line.

Applicant has not provided guidance for the introgression of male sterility or any other trait from a non-disclosed and uncharacterized parentals into the claimed variety, wherein said introgression should result in successful expression of the desired trait but should not interfere with expression of the remaining traits whose combination confers patentability to the instantly exemplified variety, and which introgression should not introduce unwanted linked genetic material into the exemplified cultivar which would disrupt its patentably unique genetic complement. The prior art does amend the deficiency. In addition, Applicant has not provided guidance regarding the genetic or the morphological characteristics of the breeding partners and their suitability to transfer a single gene of interest (the male sterile gene) into the desired cultivar.

The state of the art teaches unpredictability inherent in the introgression of a single gene trait from the genetic background of a plant into the genetic background of a different plant, to confer the phenotype in said different plant. For example, Hunsperger et al (US Patent No. 5, 523, 520) disclosed a specific gene trait in the genetic background of one plant which has been introgressed into the genetic background of another plant of the same species, that didn't result in the expected single gene converted plant (column 3, lines 26-46). Kraft et al (Theor. Appl. Genet. 2000, vol. 101, pp. 323-326) teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single transferred trait, and such that effects are

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unpredictably genotype specific and loci dependent in nature. Kraft et al teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding material, and therefore, is an unpredictable effect in plant breeding (page 323, column 1, line 7 to line 15). See, Eshed et al (Genetics, vol. 143, pp1807-1817, 1996) who teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (page 1815, column 1, line 1 to page 1816, column 1, line 1). Neither the instant specification nor the prior art provides evidence that such linkage disequilibrium, linkage drag, or epistatic effect uncommon in corn breeding materials, such that one or more transgenes can be transferred from one genetic background to another.

Therefore, given the lack of guidance in Applicants' specification regarding transfer and expression of genes by backcrossing in Applicant's corn line while retaining the other desirable genotypic and phenotypic characteristics, the lack of guidance regarding the isolation of a multitude of non-exemplified transgenes or their evaluation in particular corn genetic backgrounds, the state of the art, the unpredictability inherent in single gene transfer, and lack of working examples, the claimed invention is not enabled.

9. Claims 17-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable

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one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Claims are drawn to a method for producing inbred 2JK221, the method comprising planting and growing a collection of seed comprising seed of a hybrid having inbred 2JK221 as one parent, and seed of the inbred 2JK221. The method also comprises identifying inbred parent plants.

Applicant has only provided guidance for seed of the corn inbred line designated 2JK221, which sample of the seed is to be deposited.

Applicant has not disclosed or provided guidance for how to identify the claimed inbred plant or inbred parent plants from a collection of other plants. Applicant has not provided guidance for a repeatable process that would allow an ordinary plant breeder to reproduce the claimed seed. In fact, it is for that reason that deposit of the claimed line is required to enable the invention. Therefore, one skilled in the art would not be able to practice the claimed method without undue experimentations.

Written Description

10. Claims 12-16 and 19-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to corn plants of an undisclosed number of generations that are only known to have at least one ancestor of 2JK221 corn plant, 2JK221-derived and further derived plants obtained by repeated crossing of a 2JK221 corn plant with

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itself or with another non-2JK221 corn plant by a number of generations. The claims are also drawn to plants transformed with one or transgenes and a method for producing progeny plants comprising said one or more transgenes.

Applicant fails to provide an adequate written description to support the claimed invention. Applicant only describes inbred corn line 2JK221 having a specific combination of genotypic and phenotypic characteristics that distinguish the line from other corn lines. Applicant has not described the morphological and/or genotypic characteristics for all hybrid corn plants and seeds of claims 12-16 produced by crossing the inbred corn line 2JK221 with another unidentified corn plant. No specific morphological or genotypic characteristics that distinguish F1 hybrid corn plants/seeds from other corn plants and seeds are described. Since Applicant has not described even F1 generation plants, methods for using F1 or other hybrid plants of claims 17-19, 21 and 24 to produce subsequent generation plants of claims 20, 22-23 and 25 are similarly not described. Furthermore, since Applicant has not described the breeding partners involved in crossing with the exemplified plant, or the resultant product, Applicant has also not described methods for using the products in subsequent generations of outcrossing to uncharacterized breeding partners, or the resultant products of said multiple outcrosses as claimed in claims 29-32. The only characteristics required by the claimed plants are the expression of a combination of at least two traits, which traits are defined in relative terms that lack comparative basis (see rejection under 112, 2nd paragraph).

Claims 26-28 are included in the rejection because Applicant has not described a multitude of non-exemplified transgenes or their phenotypic effects in particular corn genetic background. In addition, the claims do not characterize the sequence or identity of the transgenes or recite phenotypic effects (claims 26 and 27). Because various breeding techniques (claims 30-31) and a number of uncharacterized breeding partners and breeding generations have been employed, substantial variation in structure and phenotypes are expected among the resultant plants. Therefore, the disclosure of a single inbred corn line 2JK221 would not provide adequate written description for all hybrid plants including F1 generation and other hybrid plants and subsequent generation plants or method for using F1 plants to produce subsequent generation plants, absent more.

Since Applicant has not described the identity of all the transgenes or their phenotypic effects, plants transformed with said transgenes and a method for producing progeny plants comprising said transgenes are similarly not described. Therefore, claimed invention lacks written description.

The Federal Circuit court stated that a written description of an invention "requires a precise definition, such as by structure, formula [or] chemical name, of the claimed subject matter sufficient to distinguish it from other material". *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997). The court also stated "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of is not a description of that material". *Id.* at 1406. Further, the court stated that to adequately describe a claimed genus, Applicant must describe a

representative number of species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of members of the genus". Id. at 1406.

Accordingly, the claimed invention lacks adequate written description as required under the current written description guidelines (See Written Description Requirement published in Federal Registry/Vol.66, No. 4/Friday, January 5, 2001/Notices; P. 1099-1111).

Claim Rejections - 35 USC § 102/103

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-16, 19-25 and 29-32 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Arthur (US 5,723,739)

The claims are drawn to F1 hybrid corn plants/seeds and subsequent generation plants produced by crossing the inbred corn line 2JK221 with unidentified corn lines.

The claims are also drawn to F1 or other types of hybrid plants and methods for using F1 and to produce subsequent generation plants by using various breeding techniques.

Arthur teaches inbred corn line designated as LH281 and a method for producing hybrid plants and seeds by crossing the LH281 plant with another corn plant and F1 hybrid and subsequent generation corn plants. The reference teaches breeding methods such as pedigree and recurrent selection breeding methods and backcrossing to transfer specific desirable trait between plants (columns 2-3). The corn plants of the instant invention and those of the prior art share morphological characteristics such as dark green leaf, glume and silk with light green color, and selected agronomic characteristics such as high yield, excellent resistance to disease, good stay green and grain quality (see at least columns 5-10). Since Applicant has not disclosed specific morphological and physiological characteristics for the claimed F1 hybrid plants or subsequent generation plants /seeds, the claimed plants are indistinguishable from those of the prior art. The claimed plants are produced from one or more crosses of the disclosed 2JK221 corn plants with any other corn plants, such that some of the disclosed physiological and morphological characteristics of 2JK221 plants would be retained. Because the claims are not limited in terms of physiological and morphological characteristics sufficient to distinguish the claimed plants from the prior art plants, the claimed invention is deemed to be anticipated by or, in the alternative, obvious over the prior art, absent evidence to the contrary.

See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejected over prior art teaching the same

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product produced by a different process, if the process of making the product fails to distinguish the two products.

Remarks

No claim is allowed.

Papers related to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmission 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday-Thursday from 8:30AM to 5:30PM and every other Friday 9:00AM to 5:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

1/24/03

Mai

A handwritten signature in black ink, appearing to read "Amy Nelson", with a stylized, flowing script.

**AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600**